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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FRANTZ, JESSICA L

ART UNIT	PAPER NUMBER
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3746

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/802,180

Applicant(s)

BRUNDLE ET AL.

Examiner

Jessica L. Frantz

Art Unit

3746

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/17/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6/17/2004, 6/27/2005.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. Applicant should note that the large number of references in the attached IDS have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. **See MPEP 609.05(b)**. Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

Specification

2. The disclosure is objected to because of the following informalities:
- On page 5, line 17 the phrase "the motor controller 26" should be changed to "the motor controller 16"
 - On page 8, lines 16 the phrase "as determined in step 240" should be changed to "as determined in step 220".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 17 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to

Art Unit: 3746

which it pertains, or with which it is most nearly connected, to make and/or use the invention. The application fails to fully describe how the controller knows the age of the tubing.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 17 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear from the claims how the motor controller is responsive to changes in the age of the tubing. Lack of rejection over the prior art should not be interpreted as indication of allowability.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 2, 10, 11, 16, 19, 20, 23, 24 rejected under 35 U.S.C. 102(b) as being anticipated by Wright et al. (4,855,660). Wright discloses the invention substantially as claimed including a sensor (20, 22) having an output; a motor controller (Microprocessor MPU, Figure 3A) having an output responsive to the sensor output; a current driver (Q1, Q2, Q3, Q4) having an electrical current output responsive to the motor controller output; and a stepper motor (18) responsive to the electrical current output. Wright

Art Unit: 3746

further discloses the sensor is responsive to changes in the position of the motor and the system includes additional sensors having outputs sent to the controller (Column 3, lines 3-11). Wright also discloses the controller has a memory containing data wherein the electrical current output is responsive to the data and the sensor output and the controller and memory are within a microcontroller. (Column 3, lines 40-45) and (Column 3, lines 3-11). Furthermore, Wright teaches a method for driving an infusion pump motor comprising the steps of determining a position in a pump cycle; and determining the electrical current value for driving the infusion pump stepper motor in response, at least in part, to the position in the pump cycle and further comprising the step of microstepping the motor. (Please see Figure 5) and wherein the position in the pump cycle and the electrical current value are related to each other in a relationship in a database (look up table in ROM Column 3, lines 3-11).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. (4,855,660) in view of Mulreany et al. (4,838,856). Wright teaches the invention substantially as claimed as discussed above but fails to teach the step of determining a flow rate, wherein the electrical current value is related to the flow rate and wherein the flow rate value is stored in a database. Mulreany teaches the step of

Art Unit: 3746

determining a flow rate, wherein the electrical current value is related to the flow rate and wherein the flow rate value is stored in a database (Column 2, lines 17-36) and (Column 7, lines 49 through Column 8, lines 1-23) (Also see Figures 5 and 7) for the purpose of maintaining a substantially constant selected flow rate. (Abstract).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the invention of Wright et al. with the step of measuring fluid flow rate and comparing it to preset values stored in a controller database for the purpose of maintaining a substantially constant selected flow rate. (Abstract).

11. Claims 12, 13, 14, 15, 21, 22, 25, 26, 27, 28, 31, 32, 33, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. (4,855,660) in view of Moberg et al. (6,659,980). Wright is discussed above and teaches the invention substantially as claimed but fails to teach the stepper motor is contained within an infusion pump under battery power wherein the output of the sensor is responsive to temperature changes and wherein the output of the sensor is sensitive to backpressure changes. Moberg teaches the stepper motor is contained within an infusion pump (101) (Column 2, lines 52-55) for the purpose of providing power to the pump. Moberg further teaches the preferred power supply is one or more batteries (Column 7, lines 39-40) for the purpose of allowing the device to be compact and wearable by the user. (Column 1, lines 61-67). Moberg further teaches the output of the sensor is responsive to backpressure changes for the purpose of detecting occlusions in the fluid path that slow, prevent, or otherwise degrade fluid delivery from the reservoir to the user's body. (Column 6, lines 6-14) and (Column 9, lines 18-45). Moberg also teaches the output of

Art Unit: 3746

the sensor is responsive to temperature changes for the purpose of ensuring an accurate reading from the backpressure sensor (Column 19, lines 21-25). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the device of Wright et al. with the teachings of Moberg et al. including the stepper motor being contained within the infusion pump for the purpose of providing power to the pump (Column 2, lines 52-55) and the power supply is one or more batteries (Column 7, lines 39-40) for the purpose of allowing the device to be compact and wearable by the user (Column 1, lines 61-67) and also the output of the sensor is responsive to backpressure changes for the purpose of detecting occlusions in the fluid path that slow, prevent, or otherwise degrade fluid delivery from the reservoir to the user's body (Column 6, lines 6-14) and (Column 9, lines 18-45) and that the output of the sensor is responsive to temperature changes for the purpose of ensuring an accurate reading from the backpressure sensor (Column 19, lines 21-25).

12. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. (4,855,660) in view of Mulreany et al. (4,838,856) as applied to claims 3 and 4 above, and further in view of Moberg et al. (6,659,980). The combined invention of Wright and Mulreany is discussed above, however they fail to teach the step of modifying the electrical current value in response to temperature information or distal pressure information. Moberg et al., as discussed above in regard to claims 12, 13, 14, 15, 21, 22, 25, 26, 27, 28, 31, 32, 33, and 34 teaches the output of the sensor is responsive to backpressure changes for the purpose of detecting occlusions in the fluid path that slow, prevent, or otherwise degrade fluid delivery from the reservoir to the

Art Unit: 3746

user's body. (Column 6, lines 6-14) and (Column 9, lines 18-45). Moberg also teaches the output of the sensor is responsive to temperature changes for the purpose of ensuring an accurate reading from the backpressure sensor (Column 19, lines 21-25) and the method of using the combined invention of Wright, Mulreany and Moberg is obvious given the structure. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the invention of Wright and Mulreany with the step of modifying the electrical current value in response to the output of a pressure sensor in order to detect occlusions in the fluid path that slow, prevent, or otherwise degrade fluid delivery from the reservoir to the user's body (Column 6, lines 6-14) and (Column 9, lines 18-45) and also in response to a temperature sensor in order to ensure an accurate reading from the backpressure sensor (Column 19, lines 21-25).

13. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. (4,855,660) in view of Mulreany et al. (4,838,856) as applied to claims 3 and 4 above, and further in view of Harriman et al. (US PG PUB 2003/0235409). The combined invention of Wright and Mulreany is discussed above but fails to teach the step of modifying the electrical current value in response to an elapsed time value or in response to the age of the infusion pump motor. Harriman teaches modifying the electric current value in response to an elapsed time value in order to determine whether or not to set the motor at an "ambient state." (Paragraphs [0016] and [0017] and Figure 4B) and also in response to the age of the infusion pump motor in order to ensure the proper motor performance (Paragraphs [0015] and [0016]). Therefore, it

Art Unit: 3746

would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the invention of Wright and Mulreany with the steps of modifying the electrical current value in response to an elapsed time value and in response to the age of the infusion pump motor in order to determine whether or not to set the motor at an "ambient state." (Paragraphs [0016] and [0017] and Figure 4B) and to ensure the proper motor performance (Paragraphs [0015] and [0016]).

14. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. (4,855,660) in view of Maske et al. (6,208,107). Wright is discussed above but fails to teach the step of half stepping the infusion pump motor. Maske teaches the step of half-stepping the motor in order to reduce excitation energy to approximately 29% of the full-step energy. (Column 3, lines 47-51). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the invention of Wright with the step of half stepping the motor in order to reduce excitation energy. (Column 3, lines 47-51)

15. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. (4,855,660) in view of Harriman et al. (US PG PUB 2003/0235409). Wright is discussed above and fails to teach the motor controller is responsive to changes in the age of the motor. Harriman teaches the motor controller is responsive to changes in the age of the motor in order to ensure the proper motor performance (Paragraphs [0015] and [0016]). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the invention of Wright with ability of the

Art Unit: 3746

motor controller to be responsive to the age of the motor in order to ensure the proper motor performance. (Paragraphs [0015] and [0016]).

16. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. (4,855,660) in view of Moberg et al. (6,659,980) as applied to claims 12, 13, 14, 15, 21, 22, 25, 26, 27, 28, 31, 32, 33, and 34 above, and further in view of Harriman et al. (US PG PUB 2003/0235409). The combined teachings of Wright and Moberg fail to teach the motor controller is responsive to changes in the age of the motor. Harriman teaches the motor controller is responsive to changes in the age of the motor in order to ensure the proper motor performance (Paragraphs [0015] and [0016]). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the invention of Wright and Moberg with ability of the motor controller to be responsive to the age of the motor in order to ensure the proper motor performance. (Paragraphs [0015] and [0016]).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Frantz whose telephone number is 571-272-5822. The examiner can normally be reached on Monday through Friday 8:30a.m.-5:00p.m. E.S.T..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ehud Gartenberg can be reached on (571)272-4828. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3746

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jessica Frantz
JF

10/30/06

Ehud Gartenberg

**EHUD GARTENBERG
SUPERVISORY PATENT EXAMINER**